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To: Undersecretary of Commerce for Intellectual Property and Director of USPTO

From: Steven L. Nichols

Fax: (571) 273-8300

Pages: 11 including coversheet

Phone:

Date: March 19, 2007

Re: Application No. 10/731,551

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1. Facsimile coversheet (1 page)
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3. Petition Under 37 CFR 1.181 (7 pages)
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Application No.: 10/731,551

Attorney Docket No.: AB-308U

## Certificate of Transmission

I hereby certify that this correspondence is being facsimile transmitted to the Commissioner for Patents via the USPTO central facsimile number, (571) 273-8300.

on March 19, 2007  
Date



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### Transmitted, herewith, are the following documents:

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10/731,551

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Patent Application of

Group Art Unit: 3762

Todd K. Whitehurst et al.

Examiner: EVANISKO, George Robert

Application No. 10/731,551

Filed: December 8, 2003

For: Fully Implantable Miniature  
Neurostimulator for Intercostal  
Nerve Stimulation as a Therapy  
for Angina PectorisPETITIONUNDER 37 C.F.R. § 1.181

Undersecretary of Commerce for Intellectual Property and  
Director of U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director:

Applicant hereby petitions under 37 C.F.R. § 1.181 that the Director review and grant relief from an improper action imposed on Applicant by the Examiner of the above-identified patent application. The Director has the right to hear this petition and grant the relief requested under 37 C.F.R. § 1.181(a)(1) and (3).

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On September 18, 2006, the Examiner issued a paper styled "Request for Information" (the "Request") in the above-identified patent application. According to the Request, the "examiner is requiring the Applicant to state on the record what nerves the applicant considers the intercostal nerve branches to consist of. ... *This information is required to extend the domain of search for prior art.*" (Request, p. 2) (emphasis added). Applicant believes this Request to be entirely improper because it does not comply with 37 C.F.R. § 1.105, because it requires, in essence, the introduction of new matter into the application and because it requires the Applicant to create unnecessary prosecution history estoppel to the detriment of Applicant and the scope of Applicant's claims. Applicant expressed these concerns to the Examiner in a subsequent response. However, the Examiner maintained the Request for Information in a subsequent action dated February 22, 2007

Although not specifically stated, the Examiner's Request is apparently made because the claims recite, for example, "implanting the stimulator adjacent to at least one tissue influencing the angina pectoris of the patient, which tissue is at least one of an intercostal nerve and an intercostal nerve branch." (Claim 1). Applicant notes that the Examiner's Request does not question or concern the claim term "intercostal nerve," but apparently becomes confused by the additional term "intercostal nerve branch." It is entirely unclear why a further statement regarding the meaning of "intercostal nerve branch(es)" is needed by the Examiner.

The Request is made under 37 C.F.R. § 1.105 which gives the examiner the ability to require the submission "of such information as may be *reasonably* necessary to properly examine or treat the matter." (37 C.F.R. § 1.105) (emphasis added). 37 C.F.R. § 1.105 also gives a

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number of examples of the type of information that may be required. However, to help the examiner “extend the domain of search for prior art” is *not* one of those examples.

It is entirely unclear to the Applicant why the Examiner is unable to determine the appropriate “domain of search for prior art.” The Examiner has *not* held the claims indefinite under 35 U.S.C. § 112, second paragraph. Indeed, the claim term at issue, “intercostal nerve branch,” is clearly a definite and recognized term in the art.

Additionally, the Office is to give each claim term its plain and ordinary meaning in the relevant art unless the specification clearly provides an alternate definition. It is inescapable that the Examiner in this instance should be able to give the claim term its plain and ordinary meaning, consistent with the specification, without further assistance from the Applicant.

As one of skill in the art, the Examiner should be able to construe Applicant’s claims in this regard and conduct an appropriate search of the prior art. Applicant notes that the Examiner of this application is a primary examiner with years of experience in this art. Therefore, it is not and cannot be “reasonably necessary” as required by 37 C.F.R. § 1.105 for the Applicant to define the scope of the prior art search for the Examiner. Therefore, Applicant believes that the Examiner’s Request is improper under 37 C.F.R. § 1.105 and cannot be imposed on the Applicant.

Applicant also believes that any construction of the claim term “intercostal nerve branches” *must* be made according to well-established and long-standing principles of law and patent practice. Specifically, Applicant considers the term “intercostal nerve branch” to refer to those nerves that are so defined in the originally-filed specification and those nerves that are so

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identified in the ordinary and customary terminology of the art at the time of the invention. *See, Markman v. Westview Instruments*, 116 S. Ct. 1384 (1996) (holding that the meaning of words used in the claims is determined by the meaning given to those words in the specification); *ZMI Corp. v. Cardiac Resuscitator Corp.*, 884 F.2d 1576, 1580, 6 U.S.P.Q.2d 1557, 1560-61 (Fed. Cir. 1988) ("words must be used in the same way in both the claims and the specification."); *McGill, Inc. v. John Zink Co.*, 736 F.2d 666, 674 (Fed. Cir. 1984); *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 759, 221 U.S.P.Q. 473 (Fed. Cir. 1984) (holding that words must be given their plain, ordinary meaning unless there is clear evidence that the inventor intended to use them differently).

As these foregoing citations clearly establish, there are well-established legal rules for ascertaining the definition of a term used in a patent claim. During examination, the USPTO gives claims their broadest reasonable interpretation. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear contrary definition in the specification. See MPEP § 2111.01.

Sitting *en banc* in 2005, the Federal Circuit clarified the guiding principles for construction of patent claims. *See Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) ("*Phillips*"). In *Phillips*, the Federal Circuit reaffirmed the time-honored rule that claim terms are generally to be given their ordinary and customary meaning to those skilled in the art:

We have frequently stated that the words of a claim "are generally given their ordinary and customary meaning." . . . We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. . . . The

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inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. 415 F.3d at 1313 (citations omitted).

The *Phillips* court was also mindful that the claims must be read in light of the specification. *Id.* at 1315 (“claims ‘must be read in view of the specification, of which they are a part’”) (citing *Markman*... 52 F.3d 967, 979 (Fed. Cir. 1995)). Importantly, the court held that claim terms should be given “*their broadest reasonable construction* ‘in light of the specification as it would be interpreted by one of ordinary skill in the art.’” *Id.* (citing *In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (emphasis added)).

The *Phillips* court repeated the venerable warning that one must “avoid the danger of reading limitations from the specification into the claim.” 415 F.3d at 1323. With that warning in mind, the court described the two primary instances in which the specification can limit the meaning of claim terms. *First*, the patentee can choose to recite an explicit definition for a claim term in the specification. *Id.* at 1316. In that case it is said that the patentee has acted as his own lexicographer and the patentee’s definition “governs.” *Id.* *Second*, the specification may limit the plain meaning of a claim term when the patentee disclaims or disavows certain interpretations of the term. *Id.* Thus, the specification can limit the plain meaning of claim terms only when the patentee has clearly set forth a limiting interpretation.

Consequently, Applicant *must* rely on any definition of the term “intercostal nerve branch” as provided in Applicant’s specification and, to an extent not inconsistent with that definition, the ordinary and customary meaning in the art at the time of the invention. If no definition is provided in the specification, Applicant *must* rely on the ordinary and customary meaning in the art at the time of invention. Given these canons of constructions, it is entirely unclear why the Examiner cannot examine Applicant’s claims without additional help. Moreover, for the Applicant to provide any other definition of the term “intercostal nerve

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branches" at this point in the examination process would be, in essence, the introduction of new matter into the application to the extent that such definition would be used to supplement or supersede the specification in construing the relevant claim terms. As the Examiner is perfectly well aware, the Applicant cannot introduce new matter into the application. MPEP § 2163.06. Moreover, the Applicant cannot add to or change what the specification itself says or doesn't say by making subsequent statements during prosecution.

Thus, in response to the Request, Applicant has stated that the nerves Applicant considers to be intercostal nerve branches are those nerves that are so defined in the originally-filed specification and those nerves that are so identified in the ordinary and customary terminology of the art at the time of the invention. No other answer is permissible.

Additionally, while it is of no consequence to the Examiner, Applicant must decline the improper Request because the Request is a requirement that the Applicant create prosecution history estoppel. As the Director will appreciate, under the principles of prosecution history estoppel, any construction Applicant provides on the record as to a claim term may ever after be applied to construe or limit the application of that claim. While Applicants have sometimes inadvertently created such estoppel on the record, the Examiner is here requiring the Applicant to create prosecution history estoppel by providing an exclusive and exhaustive list of "intercostal nerve branches." This is clearly improper and inappropriate.

MPEP § 706.07 states that the applicant should receive the cooperation of the examiner in seeking to define his or her invention in claims that will give him or her the patent protection to

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which he or she is justly entitled. Clearly, the Examiner's Request in this instance violates principle of this admonition.

Applicant further notes that the delay occasioned by this improper Request is unduly burdensome on the Applicant both financially and in terms of lost patent term.

For any and all of the foregoing reasons, the Request made by the Examiner is clearly improper. Therefore, Applicant respectfully petitions the Director to exercise his supervisory authority under 37 C.F.R. § 1.181 and withdraw the improper Request with instructions to the Examiner to proceed with the examination of the claims according to correct practice and procedure.

Authorization is hereby given to charge any fees required by this petition to Deposit Account No. 180013 in the name of Rader, Fishman & Grauer PLLC.

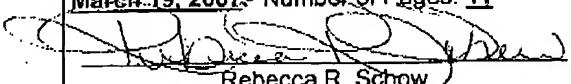
Respectfully submitted,



Steven L. Nichols  
Registration No. 40,326

DATE: March 19, 2007

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<b>CERTIFICATE OF TRANSMISSION</b>	
I hereby certify that this correspondence is being transmitted to the Patent and Trademark Office facsimile number <u>571-273-8300</u> on <u>March 19, 2007</u> . Number of Pages: <u>11</u>	
 Rebecca R. Schow	

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PTO/SB/17 (02-07)

Approved for use through 02/28/2007. OMB 0651-0032

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Effective on 12/08/2004.  
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4918).

## FEE TRANSMITTAL For FY 2007

Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** (\$)  
**400.00**

### Complete if Known

Application Number	10/731,551
Filing Date	December 8, 2003
First Named Inventor	Todd K. Whitehurst
Examiner Name	EVANISKO, George Robert
Art Unit	3762
Attorney Docket No.	AB-308U

### METHOD OF PAYMENT (check all that apply)

Check  Credit Card  Money Order  None  Other (please identify): \_\_\_\_\_

Deposit Account Deposit Account Number: 180013 Deposit Account Name: Rader, Fishman & Grauer

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

<input checked="" type="checkbox"/> Charge fee(s) indicated below	<input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee
<input checked="" type="checkbox"/> Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17	<input checked="" type="checkbox"/> Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

### FEE CALCULATION

#### 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

#### 2. EXCESS CLAIM FEES

##### Fee Description

Each claim over 20 (including Reissues)

Each independent claim over 3 (including Reissues)

Multiple dependent claims

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Small Entity Fee (\$)	Fee (\$)
- 20 or HP =	x	=		50	25

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims	Fee (\$)	Fee Paid (\$)
- 3 or HP =	x	=				

HP = highest number of independent claims paid for, if greater than 3.

#### 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	/ 50 =	(round up to a whole number) x		

#### 4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Patent Petition Fee Under 37 CFR 1.17(f)

Fee Paid (\$)

400.00

### SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 40,326	Telephone 801-572-8066
Name (Print/Type)	Steven L. Nichols		Date March 19, 2007

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.